IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit:	1612	:	
Applicant:	Morris et al.	:	VITAMIN POWDER COMPOSITIONS
Serial No.:	09/933,709	:	
Filing Date:	August 22, 2001	:	

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APPEAL BRIEF

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Applicants for the above-referenced patent application, Morris et al., submit this appeal brief in accordance with the provisions of 37 C.F.R. 41.37 in response to (i) the Office Action dated June 21, 2007, (ii) the Notice of Appeal filed November 20, 2007. The Commissioner is hereby authorized to charge Account No. 11-1110 for any fees necessary for consideration of this brief.

I. REAL PARTY IN INTEREST

The real party in interest is Archer Daniels Midland Company by reason of assignment from the inventors recorded at Reel 009738, Frame 0384.

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal and Pre-Appeal Brief Request for Review were filed on September 25, 2006. The Pre-Appeal Brief Conference resulted in the panel reopening prosecution, thus, withdrawing the previous rejection.

Applicants are not aware of any other appeals or interferences that will directly affect or be directly affected by or have a bearing on the decision of the Board of Patent Appeals and Interferences ('Board") in the present case.

III. STATUS OF CLAIMS

Claims 18-44 and 47-52 are pending in the application. All of the claims have been rejected and form the basis of this Appeal. Specifically, in the Final Office Action mailed on June 21, 2007 (hereinafter "the Office Action") pending claims 22-24, 26-28, 30, 35-44, and 47-49 are rejected under 35 U.S.C. § 112, second paragraph, for assertedly failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Also, in the Office Action, claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent No. 4,486,435 to Schmidt et al. (hereinafter "the '435 patent") in combination with U.S. Patent No. 4,603,143 to Schmidt et al. (hereinafter "the '143 patent") and U.S. Patent No. 4,719,228 to Rawlins (hereinafter "the '228 patent") or the '228 patent in view of the '435 patent or the '143 patent by themselves or in combination. In addition, in the

Office Action, claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over the '435 patent in combination with the '143 patent and the '228 patent or the '228 patent in view of the '435 patent or the '143 patent by themselves or in combination further in view of U.S. Patent No. 4,010,073 to Drake et al. (hereinafter, "the '073 patent").

IV. STATUS OF AMENDMENTS

All amendments previously submitted have been entered, except for the proposed amendments filed on September 21, 2007 in response to the Final Office Action mailed June 21, 2007. The proposed amendments were filed after a final rejection, but prior to the date of filing a brief, but were not entered because the Examiner believed that they raised new issues that would require further consideration and/or search.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Background

It is desirable to obtain free-flowing powders from fat-soluble or water-soluble vitamins. Such vitamin powders are commonly used as additives to feed mixtures or can be given to humans. The prior art has provided methods for producing vitamin powders. A common drying technique used for producing vitamin powders is spray drying. What is needed are free-flowing compositions containing an amount of at least one fat soluble vitamin and a more economical method than spray drying to produce free flowing vitamin powders.

B. Summary of Subject Matter Defined in the Independent Claims

The present application includes independent claims 18, 22 and 26 directed generally to free-flowing compositions comprising starch, silica, and at least one fat soluble vitamin. In addition, the application includes independent claim 29 directed to a product by process. Specifically, independent claim 18 of the application states:

18. A free flowing composition comprising:

about 5 to about 34 weight percent redried cornstarch;

silica having a particle size of between 40 and 50 microns; and

65 to 80 weight percent of at least one fat soluble vitamin.

Independent claims 22 and 26 include similar elements as recited in claim 18. For example, claims 22 and 26 state:

22. A free flowing composition comprising:

about 5 to about 34 weight percent starch;

silica having a density of at least 12.5 lbs./cu.ft., a particle size of between 40 and 50 microns, and a surface area of from about 400 m^2/g to 500 m^2/g; and

at least 65 to 80 weight percent of at least one fat soluble vitamin.

26. A free flowing composition comprising:

about 5 to about 34 percent starch;

silica having a particle size of between 40 and 50 microns; and

at least 65 to 80 weight percent of at least one fat soluble vitamin, wherein the composition is free of fatty acid esters of glycerine.

In addition, claim 29 states:

29. A product produced by a process, the process comprising:

mixing about 5 to about 34 weight percent starch, silica having a particle size of between 40 and 50 microns and liquid mixed tocopherols present in amounts of 65 to 80 weight percent.

C. Advantages of the Present Invention

One advantage of the present invention is a more economical alternative to spray drying to produce vitamin powders. Specifically, by using the present invention, there is a 10 percent cost reduction in manufacturing over spray dried vitamin powders. Similarly, equipment costs for producing the free flowing compositions recited in claims 18, 22, and 26 and the product recited in claim 29 would be lower than the cost of a spray drier. Furthermore, Applicants have demonstrated that the claimed combination is capable of being loaded with more vitamin than has been previously shown in the cited prior art.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the previously presented amendments should be entered as they present no new issues and would have removed issues for Appeal, such as the 35 U.S.C. § 112 rejection.

2. Whether each of claims 18-44 and 47-52 define subject matter that, as a whole, would have been obvious to one of ordinary skill in the art in view of the combined disclosures of the '435 patent in combination with the '143 patent and the '228 patent or the '228 patent in view of the '435 patent or the '143 patent by themselves or in combination.

3. Whether each of claims 18-44 and 47-52 define subject matter that, as a whole, would have been obvious to one of ordinary skill in the art in view of the combined disclosures of the '435 patent in combination with the '143 patent and the '228 patent or the '228 patent in view of the '435 patent or the '143 patent by themselves or in combination, further in view of the '073 patent.

VII. ARGUMENT

1. Whether the previously presented amendments should be entered as they present no new issues and would have removed issues for appeal, such as the 35 U.S.C. § 112 rejection.

Applicants request entry of the proposed amendments to claims 22-24, 26-28, 30, 35-44, and 47-49 as presented in the Response to Final Office Action mailed September 21, 2007. These claims 22-24, 26-28, 30, 35-44, and 47-49 were rejected under 35 U.S.C. § 112 as assertedly failing to point out and distinctly claim the invention. Claims 22 and 26 were amended to remove the term "at least," and claim 23 was amended to recite a grouping of fat soluble vitamins, as suggested by the Examiner. A review of the requested amendments shows that they present no new issues, but rather further clarify the claims. Therefore, it is respectfully requested that the previously presented amendments be entered as they present no new issues and would have removed issues for appeal.

2. Where the '143 patent reference and the '228 patent do not disclose those features that are missing from the '435 Patent, the rejection of claims 18-44 and 47-52 in view of the combination of the '435 patent and the '143 patent and the '228 patent is improper

Claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious over the '435 patent in combination with the '143 patent and the '228 patent or the '228 patent in view of the '435 patent or the '143 patent by themselves or in combination. Applicants respectfully disagree.

First, the claims are non-obvious because there is a showing of criticality of the range of 40-50 microns for silica and/or the additional physical characteristics of the silica sizes shown to be effective. These data were previously presented in the Declaration of Charles A. Morris (Sept. 4, 2003, hereinafter the "Declaration of Morris"), attached herewith in Appendix B. Table B of the Declaration of Morris '03 shows that only the 40-50 micron range (not smaller or larger sizes of silica) resulted in a free-flowing powder. Further, Mr. Morris notes that such results are entirely unexpected. *Id.* at paragraph 11.

Independent claims 18, 22, 26, and 29, all teach a free-flowing powder using a critical range of 40-50 microns of silica. Given that such a critical range exists, and that it has been conclusively demonstrated in the Declaration of Morris, Applicants respectfully request withdrawal of the rejection.

Despite the submission of the Declaration of Morris, the Examiner asserts that the Declaration is unscientific. Applicants strongly disagree with the characterization of the data in the Declaration of Morris as being "unscientific." Such a characterization of the data is "contrary to logic, reason, and the text" itself...." *See, In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986) cited in M.P.E.P §716.01(a). Mr. Morris is an expert in his field and the declaration contains scientific data that was collected in the course of a controlled experiment, and, further, the data was submitted under oath. His observations are expert, qualitative, scientific observations and such data is expressly allowed by the courts. *See, Id.* at 941, where the data consisted of a panel of expert taste testers' opinions on a coffee formulation and the Examiner erred in failing to consider the comparative qualitative data (attached). Thus, the Examiner must review the data for its probative value as required by MPEP § 716.01(c).

In asserting that the "results presented are not evaluated using scientific measuring parameters to show that the properties are patentably distinct and unexpected" and that "the results such as good, fair, very good, no and yes are merely observations, which are subjective and not 'scientific' (Final Office Action dated June 21, 2007, page 5);" the Examiner is making an unsupported assumption without any support in the record, which is not permitted by the Federal Circuit or the MPEP. The Federal Circuit has stated that "the Board [i.e., the Patent Office] cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board [i.e., the patent office] must point to some concrete **evidence in the record** in support of these findings." *See, In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001) (emphasis added). Further, the MPEP indicates that general statements made by the Examiner stating that a

declaration is insufficient to overcome a rejection without an explanation supporting such statements are insufficient. *See,* MPEP § 716.01. Thus, the record clearly establishes that the Declaration of Morris shows that the 40-50 micron range is critical to forming a free-flowing powder. The Examiner has presented no evidence to the contrary.

Further, Applicants have met the burden of showing unexpected results as detailed in MPEP § 716.02(a). In fact, the Examiner does not dispute that Mr. Morris observed that, except in the 40-50 micron range, the compositions were not free flowing. As such, the discovery of Mr. Morris is particularly important because the Examiner has stated that all sizes of silica would be free-flowing. Thus, one of skill in the art would not have predicted that a critical range existed for silica and fat soluble vitamins, much less what the critical range would be. As such, Applicants respectfully request withdrawal of the rejections.

In addition, the Examiner states that the '228 patent teaches that Sipernat 50 is free-flowing. This is an incorrect reading of the reference. The '228 patent teaches that silica ranging from 10 μm to 1 mm (including Sipernat 50) in combination with a pharmaceutically active ingredient (i.e., indomethacin, ketazolam, diazepam, digoxin, and 6-cyano-3,4-dihydro-2,2-dimethyl-trans-4-(2-oxo-1-pur-rolidinyl)-2H-benzo[b]pyran-3-ol) is free-flowing, but the '228 patent **does not** disclose or suggest combining silica with **a fat soluble vitamin**. According to the Examiner, it would be expected from reading the '228 patent that all size ranges would work with fat soluble vitamins, but, as the Declaration of Morris shows, only a relatively narrow range is actually suitable for maintaining free-flowability. Thus, without any direction or guidance to the critical claimed range or fat soluble vitamins, the '228 patent cannot render obvious (either alone or in combination) a silica particle in the 40-50 micron range which maintains free-flowability when fat soluble vitamin is absorbed at the levels recited in claims 18, 22, 26, and 29 as well as the claims dependent thereon. If anything, the '228 patent is further evidence of the failure of one of ordinary skill in the art to recognize the criticality of the recited 40-50 micron range.

The Examiner notes that Aerosil 200 (12 microns) and Aerosil R 972 (16 microns) were both gritty and therefore not free-flowing in the Declaration of Morris. As discussed, *supra*, these data confirm that unexpected results occur, because, as stated by the Examiner, "one would assume that 16 micron silica to be better than 12 micron particles." In fact, there is no indication in any of the references that higher loading densities could ever be achieved while maintaining free-flowability at any size. However, Applicants have found that despite the teachings in the art, free-flowability can be achieved for high loading densities at the critical 40-50 micron range. *See*, the specification of the instant application, paragraph [0020]. Thus, the results are unexpected and the loading density range is non-obvious.

The Examiner alleges that the data does not support a range as low as 40 microns; however, Applicants note that absent evidence to the contrary, such a small variation in size would remain "free-flowing." Since Sipernat 50 has a mean size of 50 microns, the person of ordinary skill in the art would know that some of the sizes are smaller than the mean, but remain free flowing. The data detailed in the Declaration of Morris thus support the claimed range.

A *prima facie* case of obviousness has not and cannot be established because the cited references do not alone, or in combination, teach, suggest, or motivate one of ordinary skill in the art to arrive at all the combinations of elements recited in the instant claims. Specifically, each of independent claims 18, 22, 26, and 29, recite, *inter alia*, elements of silica particle sizes of 40-50 microns AND addition of a starch AND a range of a fat soluble vitamin from 65 to 80 weight percent. As shown in the Declaration of Morris, this combination of elements is critical to achieve the free-flowing compositions having the high loading densities (up to 80%) of fat soluble vitamins. Such elements are not disclosed alone or in combination in any of the cited references. In fact, based on the cited references, one of ordinary skill in the art would not expect that such loading densities are even possible.

A prima facie case has not been established because the cited references only teach low vitamin-load compositions for silica and vitamin E, i.e., 45-60

percent vitamin as noted in the Office Action mailed January 11, 2007. Independent claims 18, 22, 26 and 29 each recite high loading densities (65-80% by weight). The Examiner asserts that 60% loading is disclosed in the '228 patent and that this is close enough to make an obviousness rejection. However, the '228 patent does not disclose loading densities with a **fat soluble vitamin** or a range of **65-80%**.

In attempting to establish obviousness, the Final Office Action states "Schmidt '143, while disclosing a free flowing, high density, fat-soluble vitamin powder preparation teaches the use of silica of bigger particle sizes (100 microns)." (Final Office Action dated June 21, 2007, page 3.) The Final Office action further states "it would have been obvious to use the silica of bigger particle sizes 40-50 microns in the compositions of the '435 patent or the '143 patent with a reasonable expectation of success, since as evidenced by the '228 patent, one can obtain free-flowing powders which have a diameter of between 10 microns to 1 millimeter, in particular 50 microns." (*Id.* at page 4.) However, the Applicants respectfully submit that the '143 patent actually teaches away from using particle sizes of 40-50 microns. As stated in the '143 patent, "the use of the described [a minimum length, width, or both of 300 microns] is **essential** to obtaining a free-flowing, fat soluble vitamin." (U.S. Patent No. 4,603,143, col. 1, lines 46-50, emphasis added.) Thus, the Applicants respectfully submit that one of ordinary skill in the art would not reasonably expect that the teachings of producing pharmaceutical powders using the silica sizes of the '228 patent would work in combination with the teachings of producing vitamin powders of the '143 patent, stating that a minimum of 300 microns is essential. Even in light of the data showing criticality, a *prima facie* case of obviousness cannot be established since the cited references do not alone, or in combination, teach, suggest, or motivate one of ordinary skill in the art to arrive at the combination of elements recited in the instant claims.

Specifically, independent claims 18, 22, 26, and 29, disclose, *inter alia*, the common elements of silica particle sizes of 40-50 microns AND addition of starch AND a range of fat soluble vitamin from 65 to 80 weight percent. As shown in

the Declaration of Morris, this combination is critical to achieve the high loading densities (up to 80%) of fat soluble vitamins, which were not be achieved in any of the cited references. *See*, the specification of the instant application, paragraph [0020]. In fact, there is no indication in any of the cited references that higher loading densities can be achieved while maintaining free-flowability, much less any direction as to how arrive at such results.

The burden of meeting a *prima facie* case is not met because the '435 patent and the '143 patent only teach low vitamin-load compositions for silica and vitamin E, i.e., 45-60 percent vitamin as noted in the Office Action. Independent claims 18, 22, 26 and 29 all recite high loading densities (65-80% by weight). The cited references do not teach what silica sizes are necessary to combine with corn starch to create free-flowing powder comprising such a high density of fat soluble vitamins. The Office Action recites the '228 patent as disclosing a 40-50 micron range of silica; however, it fails to teach why this range is important to maintaining flowability of high density loading of tocopherols or other fat soluble vitamins. In fact, there is no mention of fat soluble vitamins at all in the '228 patent. Consequently, there is no specific teaching or rationale linking corn starch and silica with the combination's ability to increase the loading density of fat soluble vitamins in a free-flowing powder.

Thus, while the Office Action has identified some of the individual elements of the claims in the cited references, the Office Action fails to teach how to combine the elements of the cited references to arrive at the recited claims, that a reasonable expectation of success would exist in combining such elements or teach the benefits associated with the claimed compositions. Instead, the Office Action recites the adage that one of skill in the art would be motivated to improve the compositions, and that the recited parameters could be arrived at by experimentation. Even if, *arguendo*, such a case could be presented, it is rebutted by the data showing the criticality of the claimed silica sizes. Thus, Applicants respectfully request withdrawal of the rejection, for at least these reasons.

Applicants further note that a reasonable explanation as to why the recited art compositions are stable is lacking. The rationale that the composition "would not be suitable for its intended purpose" as asserted in the Office Action, presupposes that the formulation would be stable. *See*, page 3 of the Office Action. Stability is a parameter that is affected by the composition, thus, stability must be demonstrated empirically. No data supports the Examiner's assertion of stability in the cited references, and, thus, Applicants respectfully obviate the rejection.

3. Where the '073 patent reference and the'143 patent and the '228 patent do not disclose those features that are missing from the '435 patent, the rejection of claims 18-44 and 47-52 in view of the combination of the '435 Patent and the '143 patent and the '228 patent and the '073 patent is improper

Claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious in the '435 patent in combination with the '143 patent and the '228 patent or the '228 patent in view of the '435 patent or the '143 patent alone or in combination; further in view of the '073 patent. Applicants respectfully disagree.

The claims are non-obvious at least because of the demonstration of a critical range of silica particles at 40-50 microns, and because the *prima facie* case has not been established as discussed herein. Furthermore, the additional '073 patent reference does not remedy the deficiencies of the previously cited references, either viewed alone or in combination. The '073 patent is used to teach that corn starch can be used to create a more stable powder comprising an enzyme. It does not stand for the proposition that starch increases flowability of oil-silica compositions, nor would one of ordinary skill in the art infer that starch would be useful for this reason, as admitted by the Examiner, stating that "the reference is used to support the contention that corn starch extends storage stability." However, Applicants reaffirm that one of ordinary skill in the art would not look to the storage stability of dismutase for the formulation chemistry of a fat soluble vitamin, especially where the admixture could affect flowability. The '073 patent does not teach how to use corn starch to improve stability of fat soluble

molecules or how such stability can be improved while maintaining the free flowability of fat soluble molecules. Thus, for at least the foregoing reason, Applicants respectfully request withdrawal of the rejections.

VIII. CONCLUSION

For the foregoing reasons, the rejection of claims 18-44 and 47-52 was improper and should be reversed.

Respectfully submitted,

June 20, 2008
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APPENDIX A

CLAIMS APPENDIX

Claims 1-17 (canceled).

18. (Previously presented) A free-flowing composition comprising:
about 5 to about 34 weight percent redried cornstarch;
silica having a particle size of between 40 and 50 microns; and
65 to 80 weight percent of at least one fat soluble vitamin.

19. (Previously presented) The composition of claim 18, wherein the at least one fat soluble vitamin is selected from the group comprising vitamin A, vitamin D, vitamin E, vitamin K, and beta carotene.

20. (Previously presented) The composition of claim 18, wherein the at least one fat soluble vitamin is liquid mixed tocopherols.

21. (Previously presented) The composition of claim 18, wherein the silica has a density of at least 12.5 lbs./cu.ft., and a surface area of from about $400m^2/g$ to $500m^2/g$.

22. (Previously presented) A free flowing composition comprising:
about 5 to about 34 weight percent starch;
silica having a density of at least 12.5 lbs./cu.ft., a particle size of between 40 and 50 microns, and a surface area of from about $400m^2/g$ to 500 m^2/g; and
at least 65 to 80 weight percent of at least one fat soluble vitamin.

23. (Previously presented) The composition of claim 22, wherein the at least one vitamin is selected from the group comprising vitamin A, vitamin D, vitamin E, vitamin K, vitamin C, vitamin B_1, vitamin B_2, vitamin B_6, vitamin B_{12}, folic acid, biotin, inositol, beta carotene, vitamin B_3, and vitamin B_5.

24. (Previously presented) The composition of claim 22, wherein the at least one vitamin comprises liquid mixed tocopherols.

25. (Canceled)

26. (Previously presented) A free flowing composition comprising:
about 5 to about 34 weight percent starch;
silica having a particle size of between 40 and 50 microns; and
at least 65 to 80 weight percent of at least one fat soluble vitamin,
wherein the composition is free of fatty acid esters of glycerine.

27. (Previously presented) The composition of claim 26, wherein the at least one fat soluble vitamin is selected from the group comprising vitamin A, vitamin D, vitamin E, vitamin K and beta carotene.

28. (Previously presented) The composition of claim 26, wherein the at least one fat soluble vitamin is liquid mixed tocopherol with a minimum assay of 700 mg/g liquid tocopherol.

29. (Previously presented) A product produced by a process, the process comprising:
mixing about 5 to about 34 weight percent starch, silica having a particle size of between 40 and 50 microns and liquid mixed tocopherols present in amounts of 65 to 80 weight percent.

30. (Previously presented) A vitamin powder comprising the composition of any one of claims 18, 22, or 26.

31. (Previously presented) The composition of claim 18, wherein the composition is stable at room temperature for at least 11 months.

32. (Previously presented) The composition of claim 31, wherein the composition is stable without special protection from light or air.

33. (Previously presented) The composition of claim 31, wherein the at least one vitamin is liquid mixed tocopherols.

34. (Previously presented) The composition of claim 33, wherein the composition is stable without special protection from light or air.

35. (Previously presented) The composition of claim 22, wherein the composition is stable at room temperature for at least 11 months.

36. (Previously presented) The composition of claim 35, wherein the composition is stable without special protection from light or air.

37. (Previously presented) The composition of claim 35, wherein the at least one vitamin is liquid mixed tocopherols.

38. (Previously presented) The composition of claim 37, wherein the composition is stable without special protection from light or air.

39. (Previously presented) The composition of claim 26, wherein the composition is stable at room temperature for at least 11 months.

40. (Previously presented) The composition of claim 39, wherein the composition is stable without special protection from light or air.

41. (Previously presented) The composition of claim 39, wherein the at least one vitamin is liquid mixed tocopherols.

42. (Previously presented) The composition of claim 41, wherein the composition is stable without special protection from light or air.

43. (Previously presented) The product of claim 29, wherein the product is stable at room temperature for at least 11 months.

44. (Previously presented) The product of claim 43, wherein the product is stable without special protection from light or air.

45. (Canceled)

46. (Canceled)

47. (Previously presented) The composition of any one of claims 18, 22 or 26, or the product of 29, wherein the silica has a particle size of about 50 microns.

48. (Previously presented) The composition of claim 22, wherein the starch is redried cornstarch.

49. (Previously presented) The composition of claim 26, wherein the starch is redried cornstarch.

50. (Previously presented) The product of claim 29, wherein the starch is redried cornstarch.

51. (Previously presented) The composition of claim 18, wherein the at least one fat soluble vitamin comprises a tocopherol.

52. (Canceled)

APPENDIX B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 6249
Morris *et al.*	Art Unit: 1615
Appl. No. 09/933,709	Examiner: Pulliam, Amy E.
Filed: Aug. 22, 2001	Atty. Docket: 1533.0520001/JAG/LAV
For: **Method of Producing Vitamin Powders**	

Declaration of Charles A. Morris Under 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Charles A. Morris, declares and states that:

1. I am a co-inventor of the above-captioned U.S. patent application number 09/933,709, filed August 22, 2001, entitled, "Method of Producing Vitamin Powders."

2. I am employed as Manager of Arkady Research with Archer Daniels Midland, in Olathe, KS, the assignee of record of the above-referenced patent application.

3. I am the subject of the *Curriculum Vitae* attached as **Exhibit A**. On the basis of the information and facts contained in these documents, I submit that I am an expert in the fields of food additives and preservatives, which includes being skilled in the arts of food processing, preservation and extrusion technology.

4. I have read and understand the subject matter of the above-captioned patent application.

5. I have read and understand the Office Action dated April 2, 2003, Paper No. 11, particularly the sections at pages 3-5 in which claims 18-46 have been rejected under 35 U.S.C. §103(a) for obviousness.

6. I have read and understand U.S. Patent No. 4,603,143 to Schmidt (US '143), cited by the Examiner in the rejection under 35 U.S.C. §103(a).

7. **Exhibit B** is a true and authentic copy of page 79 of lab notebook 018, which was created by Lee Willis under my direct supervision at the ADM laboratory facility in Arkady, Kansas. The data contained in **Exhibit B** was collected in the regular course of business as defined by Rule 803(6) of the Federal Rules of Evidence.

8. **Exhibit B** contains data that relates to the flowability and oil absorption of vitamin powders produced with the following commercial silicon dioxide products: Sipernat 22, Syloid 244 FP, Aerosil 200, Sipernat 50, Aerosil R 972, Sipernat 22S, and Sipernat 50S. Micro Cel-C and Hubersorb 600 are not silicon dioxide products, but instead are calcium silicate, therefore they are not relevant to the discussion regarding silica particle size in the production of vitamin powders.

9. The particle sizes, oil absorption, evaluation and acceptance for processing of the silicon dioxide products listed in **Exhibit B** are represented in the chart below:

Name	Size	Oil Absorption	Evaluation	Acceptance for Processing
Syloid 244 FP	3 microns	fair-good	chunky	no
Sipernat 22S	7 microns	good to very good	chunky	no
Sipernat 50S	7.5-8 microns	fair-good	chunky	no
Aerosil 200	12 microns	very good	gritty	yes
Aerosil R 972	16 microns	very good	very gritty	no

Name	Size	Oil Absorption	Evaluation	Acceptance for Processing
Sipernat 50S	50 microns	good	smooth	yes
Sipernat 22	100 microns	very poor	chunky	no

10. **Exhibit B** shows flowability and oil absorption data for vitamin powders produced with silica of sizes ranging from 3 microns to 100 microns. This data shows that of all the silicon dioxide tested, Sipernat 50 (50 microns) produced a "smooth" end product. "Smooth," as used to describe the properties of the vitamin powders in **Exhibit B** indicates that the powder is free-flowing. The "gritty" and "chunky" vitamin powders produced with silicon dioxide outside the 40-50 micron particle size range were not free-flowing as is contemplated by the above-captioned patent application. Thus, the use of silicon dioxide particles within the 40-50 micron size range is necessary to produce the free-flowing vitamin powders of the above-captioned application.

11. Based on the data collected relating to vitamin powders produced with silica particles outside the 40-50 micron size range, it was an unexpected discovery that the 40-50 micron silicon dioxide particle size range was so important to successful production of the free-flowing vitamin powders of the present invention.

12. I have read and understood 37 C.F.R. § 10.18 (b) and (c).

9-4-03
Date

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Direct work in laboratory on the development of new ingredients and applications. Provide direct support for customers in the use of ADM ingredients in the bakery, cereal , specialty mix and snack areas. Will support ADM products by providing technical information through presenting seminars and contributing information articles in professional food trade publications.

Technical Service Manager ADM Arkady

Ogilvie Mills Inc. was purchased July 1992 by Archer Daniels Midland. I am the Technical Service contact at ADM Arkady providing technical information for customers interested in wheat starch, wheat gluten, dry honey, dry molasses and enrichments. I direct application work that would use these products in bakery and non-bakery applications. After ADM purchased Ogilvie I worked with ADM's corn processing division in Decatur, I was doing technical service work with ADM's corn sweeteners plus Ogilvie products. Company expert on drum drying starch and sweeteners.

Principal accountabilities:
- Provide technical assistance to national and international customers through correspondence and field trips.
- Direct product application in the development of new products and customer applications.
- Write ingredient specifications for dry sweetener products and starch gluten products.
-Develop product specifications for dry honey and molasses products.
- Write Material Safety Data Sheets.
- Update and produce new product data sheets for food ingredients.
- Development of Quality Control procedures and methods for laboratory.
- Computer coordinator for ADM Arkady.

1985 to July, 1992
Ogilvie Mills, Inc.
Minneapolis, MN

Technical Service Manager
Ogilvie Mills, Inc. purchased the Food Ingredients Division of Henkel Corporation in 1985. I worked as Technical Service Manager providing technical service in support of company sales of starch, gluten, Dry honey, dry molasses, dry malt, pea fiber and specialty vitamin blends.
Principal accountabilities:
- Provide technical assistance to national and international customers through correspondence and field trips.
- Direct product application laboratory in the development of new products and customer applications.
- Write ingredient specifications for dry sweetener products.
- Develop product specifications for dry honey and molasses products.

- Write Material Safety Data Sheets.
- Update and produce new product data sheets for food ingredients.

1977 - 1985
Henkel Corporation
Minneapolis, MN

General Mills Chemicals, Inc. was purchased by Henkel Corporation. Continued to work in Process Development, food ingredients area. Worked at both production plant and pilot plant levels with wheat starch, gluten and dry honey and dry molasses. Major project was the start-up of new products on single and double roll drum dryer. Work on startup of starch gluten production plant.

1976 - 1977
General Mills Chemicals, Inc.
Minneapolis, MN

Developmental Technician - worked in laboratory and pilot plant on new chemical development. Major areas worked in were guar gums, lix reagents and distillation of sterols.

Patents

U.S. Patent 4,501,758 Honey Coated Nuts
U.S. Patent 4,738,865 Coating Adhesive (food grade)
U.S. Patent 4,800,097 Dried Nutmeat and Starch Food Product and Process (drum dryer)
U.S. Patent 4,919,956 Methods for Drying Honey and Molasses (extruder)
U.S. Patent 4,981,707 Dextrin-Based Food-Grade Adhesive Including Xanthan or Carboxymethylcellulose or Mixtures Thereof
U.S. Patent 6,303,167 Dry vitamin powder

Education

1975
University of Tampa
Tampa, Florida
Bachelor of Science, Major: Biology
Minor: Chemistry

Professional Memberships

Institute of Food Technology Professional Member
American Association of Cereal Chemists
American Society of Bakery Engineers
American Oil Chemist Socity

Exhibit B
Appl. No. 09/933,709

Vitalex -60

Project No.____
Book No. 018

ge No.__

urpose To determine if we can produce a product similar to o-crust-60 from Breddo

Do Crust-60 Ingred Legend, EOM, wheat flour + Silicon Dioxide

	#1	#2	#3	#4	#5	#6	#7	#8
thoxylated Mono	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0
Wheat Flour	20.0	30.0	20.0	20.0	20.0	20.0	10.0	15.0
Zeosil 200	20.0	—	—	—	—	—	—	—
yloid 244		10.0	—	—	—	20.0	—	—
ipernat 50		—	20.0	—	—	—	—	25.0
ipernat 22		—	—	20.0	—	—	—	—
alcium Silicate		—	—		20.0	—	30.0	—
	**	**	**	**	**	**	OK	OK

* Would not pep well, too caky
* Would not process very well in production.

Oil absorption Evaluation (3:1 oil/carrier)

	Oil absorption	acceptance for processing
Sipernat 22	V. Poor, chunky	No
Micro Cel-C	Good, some dark	Yes
Syloid 244 FP	Fair-Good chunky	No
Zeosil 200	Very Good, gritty	Yes +
Sipernat 50	Good, Smooth	Yes +
Zeosil R 932	V. Good, very gritty	No
Sipernat 22S	Good-V. Good, chunky	No
Sipernat 50S	Fair-Good, chunky	No
Hubersorb 600	Very Good, sl. gritty	Yes +

	#9
thoxylated Mono	75.0%
ipernat 50	25.0

To Page No.____

TOTAL P.01